1632

FULBRIGHT & JAWORSKI L.L.P.
A REGISTERED LIMITED LIABILITY PARTNERSHIP
600 CONGRESS AVENUE, SUITE 2400
AUSTIN, TEXAS 78701-3271
WWW.FULBRIGHT.COM

STEVEN L. HIGHLANDER
PARTNER
SHIGHLANDER@FULBRIGHT.COM

DIRECT DIAL: (512) 536-3184
TELEPHONE: (512) 474-5201
FACSIMILE: (512) 536-4598

October 2, 2003

CERTIFICATE OF HAND DELIVERY

I hereby certify that this correspondence is being hand delivered for filing to: Examiner Thian N. Ton, Group 1632, Commissioner for Patents, Washington, D.C. 20231, on the date below:

October 2, 2003 (Date) Alicia Siddiqui (Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 09/558,472 entitled "DIAGNOSIS AND TREATMENT OF MYOCARDIAL FAILURE" – Michael R. Bristow et al.*
Our reference: MYOG:004USD1

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references B1, C1, C4-C11, C15, C17, C21, C26, C28-C30, C32-C33, C45-C46, C48-C52, C56, C59-C60.

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of $180.00 is enclosed herewith. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/MYOG:004USD1.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Steven L. Highlander
Reg. No. 37,642

SLH/kmv
Encl.: as noted

25339633.1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Michael R. Bristow *et al.*

Serial No.: 09/558,472

Filed: April 25, 2003

For: DIAGNOSIS AND TREATMENT OF MYOCARDIAL FAILURE

Group Art Unit: 1632

Examiner: Thian N. Ton

Atty. Dkt. No.: MYOG:004USD1

10/08/2003 HMARZI1 00000020 09558472
01 FC:1806 180.00 OP
10/08/2003 HMARZI1 00000020 09558472
01 FC:1806 -180.00 OP

10/08/2003 HMARZI1 00000063 09558472
01 FC:1806 180.00 OP

CERTIFICATE OF HAND DELIVERY

I hereby certify that this correspondence is being hand delivered for filing to: Examiner Thian N. Ton, Group 1632, Commissioner for Patents, Washington, D.C. 20231, on the date below:

October 2,2003
Date

Alicia Siddiqui
Signature

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

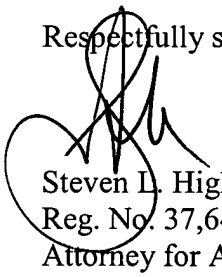
In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This application is a divisional application of Serial No. 09/016,075, filed January 30, 1998, which claims priority to U.S. Provisional application Serial Nos. 60/036,987 filed January 30, 1997 and 60/038,911 filed February 26, 1997 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) only copies of those documents not previously cited and submitted to the Patent and Trademark Office in prior application Serial No. 09/016,075 are enclosed for the convenience of the Examiner.

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of $180.00 is enclosed herewith. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/MYOG:004USD1.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Steven L. Highlander
Reg. No. 37,642
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: September 30, 2003

Form PTO-1449 (modified)	Atty. Docket No. MYOG:004USD1	Serial No. 09/558,472
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant Michael Bristow *et al.*	
	Filing Date: April 25, 2000	Group: 1632

U.S. Patent Documents	Foreign Patent Documents	Other Art
See Page 1	*See Page 1*	*See Page 1*

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	5,219,727	6/15/93	Wang *et al.*	435	6	9/28/89
	A2	5,476,774	12/19/95	Wang *et al.*	435	91.2	03/09/93
	A3	5,580,722	12/03/96	Foulkes *et al.*	435	6	02/07/92

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO00/15821	03/23/00	PCT			

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Alexander *et al.*, "Gene transfer and models of gene therapy for the myocardium," *Clin. Exp. Pharmacol. Physiol.*, 26:661-668, 1999.
	C2	Arai *et al.*, "Alterations in sarcoplasmic reticulum gene expression in human heart failure," *Circulation Research*, 72(2):463-469, 1993.
	C3	Boluyt *et al.*, "Alterations in cardiac gene expression during the transition from stable hypertrophy to heart failure," *Circ. Res.*, 75:23-32, 1994.
	C4	Bouvagnet *et al.*, "Distribution pattern of α and β myosin in normal and diseased human ventricular myocardium," *Basic Res. Cardiol.*, 84:91-102, 1989.
	C5	Bristow *et al.*, "Reduced β1 receptor messanger RNA abundance in the failing human heart," *J. Clin. Invest.*, 92:2737-2745, 1993.
	C6	Calovini *et al.*, "Steroid-hormone regulation of myosin subunit expression in smooth and cardiac muscle," *Journal of Cellular Biology*, 59:69-78, 1995.
	C7	Chen *et al.*, "Regulation of human cardiac myosin heavy chain genes: the effect of catecholamine," *Biochemical and Biophysical Research Communications*, 188(2):547-553, 1992.

25339629.1

EXAMINER:	DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)	Atty. Docket No. MYOG:004USD1	Serial N . 09/558,472
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT	Applicant Michael Bristow *et al.*	
(Use several sheets if necessary)	Filing Date: April 25, 2000	Group: 1632

U.S. Patent Documents	Foreign Patent Documents	Other Art
See Page 1	*See Page 1*	*See Page 1*

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C8	Coffin *et al.*, "Gene delivery to the heart in vivo and to cardiac myocytes and vascular smooth muscle cells in vitro using herpes virus vectors," *Gene Therapy*, 3:560-566, 1996.
	C9	Colucci and Branwald, In: *Heart Disease: A Textbook of Cardiovascular Medicine*, (Braunwald ed., 5th ed.), Chapter 13, 406, 1997.
	C10	Davidson *et al.*, "Cardiac gene delivery with cardiopulmonary bypass," *Circulation*, 104:131-133, 2001.
	C11	del Monte *et al.*, "Improvement in survival and cardiac metaboliam after gene transfer of sarcoplasmic reticulum Ca2+-ATPase in a rat model of heart faliure," *Circulation*, 104:1424-1429, 2001.
	C12	Feldman *et al.*, "Selective gene expression in failing human heart," *Circulation*, 83(6):1866-1872, 1991.
	C13	Flink *et al.*, "Atrial and ventricular cardiac myosins contain different heavy chain species," *FEBS Letters*, 94(1):125-130, 1978.
	C14	Flink *et al.*, "Interaction of thyroid hormone receptors with strong and weak sis-acting elements in the human α-myosin heavy chain gene promoter," *Journal of Biological Chemistry*, 265(19):11233-11237, 1990.
	C15	Fromes *et al.*, "Gene delivery to the myocardium by intrapericardial injection," *Gene Therapy*, 12:683-688, 1999.
	C16	Gustafson *et al.*, "Thyroid hormone regulates expression of a transfected α-myosin heavy-chain fusion gene in fetal heart cells," *Proc. Natl. Acad. Sci., USA*, 84:3122-3126, 1987.
	C17	Hajjar *et al.*, "Modulation of ventricular function through gene transfer in vivo," *Proc. Natl. Acad. Sci., USA*, 95:5251-5256, 1998.
	C18	Hanatani *et al.*, "Inhibition by angiotensin II type 1 receptor antagonist of cardiac phenotypic modulation after myocardial infarction," *J. Mol. Cell Cardiol.*, 27:1905-1914, 1995.
	C19	Hixson *et al.*, "α-myosin heavy chain cDNA structure and gene expression in adult, fetal, and premature baboon myocardium," *J. Mol. Cell Cardiol.*, 21:1073-1086, 1989.
	C20	Izumo *et al.*, "Myosin heavy chain messenger RNA and protein isoform transitions during cardiac hypertrophy," *J. Clin. Invest.*, 79:970-977, 1987.

25339629.1

EXAMINER:	DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)	Atty. Docket No. MYOG:004USD1	Serial No. 09/558,472
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT	Applicant Michael Bristow *et al.*	
(Use several sheets if necessary)	Filing Date: April 25, 2000	Group: 1632

U.S. Patent Documents	Foreign Patent Documents	Other Art
See Page 1	*See Page 1*	*See Page 1*

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C21	Jones *et al.*, "Ablation of the murine α myosin heavy chain gene leads to dosage effects and functional deficits in the heart," *J. Clin. Invest.*, 98:1905-1917, 1996.
	C22	Kashani-Sabet *et al.*, "Detection of drug resistance in human tumors by in vitro enzymatic amplification," *Cancer Research*, 48:5775-5778, 1988.
	C23	Katz, "Cardiomyopathy of overload," *New England J. of Medicine*, 322(2):100-110, 1990.
	C24	Kurabayashi *et al.*, "Molecular cloning and characterization of human cardiac α- and β-form myosin heavy chain complementary DNA clones," *J. Clin. Inves.*, 82:524-531, 1988.
	C25	Kurabayashi *et al.*, "The myosin gene switching in human cardiac hypertrophy," *Japanese Circulation Journal*, 54:1192-1205, 1990.
	C26	Kypson *et al.*, "Ex vivo adenovirus-mediated gene transfer to the adult rat heart," *J. Thorac. Surg.*, 115:623-630, 1998.
	C27	Ladenson *et al.*, "Reversible alterations in myocardial gene expression in a young man with dilated cardiomyopathy and hypothyroidism," *Proc. Natl. Acad. Sci., USA*, 89:5251-5255, 1992.
	C28	Lazarous *et al.*, "Adenoviral-mediated gene transfer induces sustained pericardial VEGF expression in dogs: effect on myocardial angiogenesis," *Cardiovasc. Res.*, 44:294-302, 1999.
	C29	Lee *et al.*, "Cardiac gene transfer by intracoronary infusion of adenovirus vector-mediated reporter gene in the transplanted mouse heart," *J. Thorac. Cardiovasc. Surg.*, 111:246-252, 1996.
	C30	Lenhart *et al.*, "Preservation of myocardial function after adenoviral gene transfer in isolated myocardium," *Am. J. Physiol. Heart Circ. Physiol.*, 279:H986, 2000.
	C31	Lévesque *et al.*, "Determination of changes in specific gene expression by reverse transcription PCR using interspecies mRNAs as internal standards," *Biotechniques*, 17(4):738-741, 1994.
	C32	Li *et al.*, "Efficient and long-term intracardiac gene transfer in δ-sarcoglycan-deficiency hamster by adeno-associated virus-2 vectors," *Gene Ther.*, 21:1807-1813, 2003.
	C33	Lin *et al.*, "Expression of recombinant genes in myocardium in vivo after direct injection of DNA," *Circulation*, 82:2217-2221, 1990.
	C34	Lowes *et al.*, "Assessment of gene expression in endomyocardial biopsy specimens from failing and nonfailing human hearts," *J. Investigative Med.*, Abstracts, 316A, 1995.

25339629.1

EXAMINER:	DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)	Atty. Docket No. MYOG:004USD1	Serial No. 09/558,472
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant Michael Bristow *et al.*	
	Filing Date: April 25, 2000	Group: 1632

U.S. Patent Documents	Foreign Patent Documents	Other Art
See Page 1	*See Page 1*	*See Page 1*

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C35	Lowes *et al.*, "Downregulation of α-and upregulation of β-myosin heavy chain in intact, failing human ventricles," Abstract, American College Cardiol. 46th Annual Scientific Session, 2/97.
	C36	Lowes *et al.*, "Changes in gene expression in the intact human heart," *J. Clin. Invest.*, 100(9):2315-2324, 1997.
	C37	Minobe *et al.*, "In vivo measurement of myocardial gene expression in the human heart," *JACC*, 277A, 1995.
	C38	Mittman *et al.*, "Analysis of gene expression patterns in small amounts of human ventricular myocardium by a multiplex Rnase protection assay," *J. Mol. Med.*, 76:133-140, 1998.
	C39	Morkin *et al.*, "Regulation of human cardiac myosin heavy chain gene expression by thyroid hormone," *Cellular and Molecular Mechanisms in Hypertension*, 143-147, 1991.
	C40	Morkin *et al.*, "Regulation of myosin heavy chain genes in the heart," *Circulation*, 87(5):1451-1460, 1993.
	C41	Morkin *et al.*, "Biochemical and physiologic effects of thyroid hormone on cardiac performance," *Progress in Cardiovascular Disease*, 25(5):435-464, 1983.
	C42	Morkin *et al.*, "Replacement of myosin during development of cardiac hypertrophy," *Supplement III to Circulation Research*, 34 & 35:111-50-111-57, 1974.
	C43	Nagai *et al.*, "Myosin isozyme synthesis and mRNA levels in pressure-overload rabbit hearts," *Circulation Research*, 60:692-699, 1987.
	C44	Nakao *et al.*, "Alpha myosin heavy chain gene expression in non-failing and end-stage failing human left ventricles," *J. Clin. Invest.*, 100(9):2362-2370, , 1997.
	C45	O'Donnell *et al.*, "Tight control of exogenous SERCA expression is required to obtain acceleration of calcium transients with minimal cytotoxic effects in cardiac myocytes," *Circ. Res.*, 88:415-421, 2001.
	C46	Pachucki *et al.*, "Type 2 iodothyronin deiodinase transgene expression in the mouse heart causes cardiac-specific thyrotoxicosis," *Endocrinology*, 142:13, 2001.
	C47	Pennock *et al.*, "Cardiac effects of 3,5-diiodothyropropionic acid, a thyroid hormone analog with inotropic selectivity," *Journal of Pharmacology and Experimental Therapeutics*, 263(1):163-169, 1992.
	C48	Rench *et al.*, "Adolescents and health heart living," *Fla Nurse.*, 49(3):16, 2001.

25339629.1

EXAMINER:	DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)	Atty. Docket No. MYOG:004USD1	Serial No. 09/558,472
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant Michael Bristow *et al.*	
	Filing Date: April 25, 2000	Group: 1632

U.S. Patent Documents	Foreign Patent Documents	Other Art
See Page 1	*See Page 1*	*See Page 1*

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C49	Schroder *et al.*, "Immune response after adenoviral gene transfer in syngeneic heart transplants: effects of anti-CD4 monoclonal antibody therapy," *Transplantation*, 70:191-198, 2000.
	C50	Shinmura *et al.*, "Catheter-Delivered in vivo gene transfer into rat myocardium using the fusigenic liposomal mediated method," *Japan Heart J.*, 41:633, 2000.
	C51	Silva *et al.*, "Reduced cardiac hypertrophy and altered blood pressure control in transgenic rats with the human tissue kallikrein gene," *FASEB*, 14:1858, 2000.
	C52	Stratford-Perricaudet *et al.*, "Widespread long-term gene transfer to mouse skeletal muscles and heart," *J. Clin. Invest.*, 90:626-630, 1992.
	C53	Tsika *et al.*, "Thyroid hormone regulates expression of a transfected human α-myosin heavy-chain fusion gene in fetal rat heart cells," *Proc. Natl. Acad. Sci., USA*, 87:379-383, 1990.
	C54	Umeda *et al.*, "Control of myosin heavy chain expression in cardiac hypertrophy," *Am. J. Cardiol.*, 59:49A-55A, 1987.
	C55	Umeda *et al.*, "Sequences of the rabbit beta myosin heavy chain promoter produce a condition of chronic heart failure in transgene mice," *Circulation*, Suppl., 84(8): 1408, Abatract 2378, 1996.
	C56	von Harsdorf *et al.*, "Gene injection into canine myocardium as a useful model for studying gene expression in the heart of large mammals," *Circ. Res.*, 72:688-695, 1993.
	C57	Vrana *et al.*, "Application of quantitative RT-PCR to the analysis of dopamine receptor mRNA levels in rat striatum," *Molecular Brain Research*, 34:127-134, 1995.
	C58	Wang *et al.*, "Quantitation of mRNA by the polymerase chain reaction," *Proc. Natl. Acad. Sci., USA*, 86:9717-9721, 1989.
	C59	Wickenden *et al.*, "Targeted expression of a dominant-negative K(v)4.2 K(+) channel subunit in the mouse hea," *Circu. Res.*, 85:1067, 1999.
	C60	Yue *et al.*, "Microdystrophin Gene Therapy of Cardiomyopathy Restores Dystrophin-Glycoprotein Complex and Improves Sarcolemma Integrity in the Mdx Mouse Heart," *Circulation*, 2003.

EXAMINER:	DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.